STATE OF MAINE

APPLICATION FOR A RADIOACTIVE MATERIAL LICENSE FOR MEDICAL USE

INSTRUCTIONS: *This application complies with the license requirements of Section C of the State of Maine Rules Relating to Radiation Protection (SMRRRP). Complete items 1 through 12. Supplemental sheets may be needed for items 5 through 11. Mail the completed application to:* **Radiation Control Program, 11 State House Station, Augusta, Maine, 04333. Telephone: (207) 287-5676.**

The Department of Health and Human Services does not discriminate on the basis of disability, race, color, creed, gender, age or national origin in admission to, access to, or operations of its programs, services or activities, or its hiring or employment practices. This information is available in alternate formats upon request.

1. THIS IS AN APPLICATION FOR (check one)

	NEW LICENSE	LICENSE NUMBER (leave blank)
	RENEWAL of license number >	
	AMENDMENT of license number >	

2. NAME AND MAILING ADDRESS OF APPLICANT	**3. ADDRESS(ES) WHERE MATERIAL WILL BE USED AND/OR STORED.**
PHONE:	PHONE:

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

NAME:_____ PHONE:_____ EMAIL: _____ .

For items 5 through 11, the requested information may be submitted on standard size paper. Answer all items. For any that do not apply, answer by giving the item number with "not applicable" after it.

5. RADIOACTIVE MATERIAL and
6. PURPOSE AND USE

A: Radioactive Material for medical use: Please place an "X" next to all the disciplines you wish to be licensed for.

Yes	Radioisotope	Form or Manufacturer /Model No.	Maximum Quantity	Purpose of Use
	Any radioactive material permitted by G.100	Any	As needed	Any uptake, dilution, and excretion study permitted by G.100.
	Any radioactive material permitted by G.200	Any	As needed	Any imaging and localization study permitted by G.200.
	Any radioactive material permitted by G.300	Any	_____ millicurie	Any radiopharmaceutical therapy procedure permitted by G.300.
	Iodine-131	Any	_____ millicurie	Administration of I-131 sodium iodide.
	Radioactive material permitted by G.400 (Radionuclide _____)	Sealed sources (Manufacturer _____, Model No._____)	_____ millicurie	Any brachytherapy procedure permitted by G.400.

Yes	Radioisotope	Form or Manufacturer /Model No.	Maximum Quantity	Purpose of Use
	Radioactive material permitted by G.400 (Radionuclide _____)	Sealed sources (Manufacturer _____, Model No._____)	_____ millicurie	Any brachytherapy procedure permitted by G.400.
	Radioactive material permitted by G.400 (Radionuclide _____)	Sealed sources (Manufacturer _____, Model No._____)	_____ millicurie	Any brachytherapy procedure permitted by G.400.
	Radioactive material permitted by G.400 (Radionuclide _____)	Sealed sources (Manufacturer _____, Model No._____)	_____ millicurie	Any brachytherapy procedure permitted by G.400.
	Strontium-90	Sealed sources (Manufacturer _____, Model No._____)	_____ millicurie	Treatment of superficial eye conditions using an applicator distributed pursuant to C.11.K. and permitted by G.400.
	Radioactive material permitted by G.500 Check all that apply: ❑ Gd-153 ❑ I-125 ❑ Other, describe	Sealed sources (Manufacturer _____, Model No._____)	As needed	Diagnostic medical use of sealed sources permitted by G.500 in compatible devices registered pursuant to C.7.
	Iridium-192	Sealed sources (Manufacturer _____, Model No._____)	_____ curies per source and _____ curies total	One source for medical use permitted by G.600, in a **Manufacturer** _____ **Model No.**_____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed sources (Manufacturer _____, Model No._____)	_____ curies per source and _____ curies total	One source for medical use permitted by G.600, in a **Manufacturer** _____ **Model No.**_____ teletheray unit. One source in its shipping container as necessary for replacement of the source in the teletherapy device.
	Cobalt 60	Sealed sources (Manufacturer _____, Model No._____)	_____ curies per source and _____ curies total	For medical use permitted by G.600, in a **Manufacturer** _____ **Model No.**_____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the source in the stereotactic radiosurgery device.
	Any radioactive material under C.6.F.	Prepackaged kits	_____ millicurie	*In-vitro* studies.
	Depleted uranium	Metal	_____ kilograms	Shielding in a teletherapy unit.

Yes	Radioisotope	Form or Manufacturer /Model No.	Maximum Quantity	Purpose of Use
	Depleted uranium	Metal	_____ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, tranmsmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No._____)	_____ millicurie	For use in a Manufacturer _____ Model No._____ _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No._____)	_____ millicurie per source and _____ millicurie total	Use as an anatomical marker.
	Plutonium (principal radionuclide PU-238)	Sealed Sources	_____millicuries per source and _____grams total	As a component of Manufacturer _____ Model No._____ nuclear-powered cardiac pacemakers for clical evaluation in accordance with manufacturer's protocol dated _____. The authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other (please specify)	Form or Manufacturer/Model No. _____	_____ millicurie	Purpose of use _____.

If Financial Assurance is required then ***Evidence of Financial Assurance must be provided***

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7.1 RADIATION SAFETY OFFICER (RSO):

Name:	Telephone:	Fax:	e-mail:

	Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO
	OR Copy of the certification(s) for the board(s) recognized by the Agency and is applicable to the types of use for which he or she has RSO responsibilities
	OR Training and Experience and Preceptor Statement (Form HHE-853) is provided.

	Provide a description of recent related continuing education and experience as required by G.22, if applicable.

	We have established, in writing, the authority, duties, and responsibilities of the RSO.

	We will ensure that the RSO is authorized to stop unsafe operation; and has sufficient time to perform radiation safety duties and responsibilities.

7.2 AUTHORIZED USERS (AUs) NAMES AND REQUESTED USES FOR EACH INDIVIDUAL: List the names of all proposed Authorized Users and the uses requested. Provide a previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) that authorizes the uses requested or complete a Training and Experience and Preceptor Statement Form (HHE853) for each individual and provide a copy of the certification(s) for the board(s) recognized by the Agency under Part G; Subparts D, E, F, G, H, and as applicable to the use requested. Provide a description of recent related continuing education and experience as required by G.22, if applicable.

7.3 AUTHORIZED NUCLEAR PHARMACIST (ANP):

Name:	Telephone:	Fax:	e-mail:

	Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named ANP;
	OR Copy of the certification(s) for the radiopharmacy board(s) recognized by the Agency under G. 20 or G. 980;
	OR Training and Experience and Preceptor Statement (Form HHE-853).

	Provide a description of recent related continuing education and experience as required by G.22, if applicable.

7.4 AUTHORIZED MEDICAL PHYSICIST (AMP):

Name:	Telephone:	Fax:	e-mail:

	Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) on which the individual was specifically named as an AMP for the units requested
	OR Copy of the certification(s) for the board(s) recognized by the Agency under G. 19 or G.961
	OR Training and Experience and Preceptor Statement (Form HHE-853) is provided.

	Provide a description of recent related continuing education and experience as required by G.22, if applicable.

8. SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

	We will provide adequate safety instruction for individuals working with or in the vicinity of licensed material in accordance with Parts G and J. (Appendix J to NUREG 1556, Vol. 9 or equivalent)

9. FACILITIES AND EQUIPMENT:

9.1 Facility Diagram: Provide the following on the facility diagrams. (Drawings will be to scale and indicate scale) **:**

	Location, room number(s), and principal use of each room or area where radioactive material is prepared, used or stored.

	Location, room number(s), and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms. Indicate whether the room is a restricted or an unrestricted area as defined in D. 3.

	Description and of the rooms where patients will be housed if they cannot be released under G.30. (This should include room number(s) and a description of the shielding, if applicable).

	Shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used.

	The directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

9.2 Radiation Monitoring Instruments

	Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations

AND/OR

	We have developed and will implement and maintain the written survey meter calibration procedures in accordance with the requirements of D.17 and that meet the requirements of G.24. (Appendix K to NUREG 1556, Vol. 9 or equivalent)

AND

	Provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

AND

	We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

9.3 Dose Calibrator And Other Dosage Measuring Equipment

	Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

9.4 Therapy Unit – Calibration And Use

	Provide the procedures required by G.609, G.610, and G.611, if applicable to the license application.

9.5 Other Equipment And Facilities

	Provide a description of additional facilities and equipment.

For manual brachytherapy facilities

	Provide a description of emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

	Warning systems and restricted area controls for each therapy treatment room;
	Area radiation monitoring equipment;
	Viewing and intercom systems (except LDR units);
	Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment are in the treatment room;
	Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
	Emergency response equipment.

10.RADIATION PROTECTION PROGRAM:

10.1 Safety Procedures And Instructions

	Provide the procedures required by G.604.

10.2 Occupational Dose

	We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive , in one year, a radiation dose in excess of 10% of the allowable limits in Part D.
	OR we will provide dosimetry that meets the requirements listed under "Criteria" in article 8.22 of NUREG 1556, Vol. 9.

OR

	Provide a description of an alternative method for demonstrating compliance with the regulations.

10.3 Area Surveys

	We have developed and will implement and maintain written procedures for area surveys in accordance with D.5. that meet the requirements of D.17 and G.29. (Appendix R to NUREG 1556, Vol. 9. or equivalent)

10.4 Safe Use Of Unsealed Licensed Material

	We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meets the requirements of D.5. and D.14. (Appendix T to NUREG 1556, Vol. 9. or equivalent)

10.5 Spill Procedures

	We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with D.5. (Appendix N to NUREG 1556, Vol. 9. or equivalent)

10.6 Installation, Maintenance, Adjustment, Repair, And Inspection Of Therapy Devices Containing Sealed Sources

	We will contract with personnel who are licensed by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee.

OR

	Name of proposed employee and types of activities requested:
	Provide a description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested, and
	Provide a copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

10.7 Public Dose

	We will ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will nor exceed 0.02 mSv (2mrem) in any one hour from licensed operations.

	We will ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1mSv (10 mrem) (TEDE) in one year from these emissions.

	We will control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

10.8 Opening Packages

	We have established and will maintain and retain written procedures for safely opening packages to ensure that the monitoring requirements of D.32. are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. (Appendix P to NUREG 1556, Vol. 9 or equivalent)

10.9 Procedures For Administrations When A Written Directive Is Required

	We have developed and will implement and maintain written procedures to provide high confidence that licensed material is administered as directed by authorized users in accordance with G.16. (Appendix S to NUREG 1556, Vol. 9 or equivalent)

10.10 Release Of Patients Or Human Research Subjects

	We will provide radiation written safety instructions to patients or human research subjects (or their parent, guardian or caregiver) released in accordance with G.30. (Appendix U to NUREG 1556, Vol. 9 or equivalent)

10.11 Mobile Nuclear Medicine Services

	We will comply with the requirements of G.31 and G.612, as applicable, as well as all other applicable regulations. (Appendix V to NUREG 1556, Vol. 9. or equivalent)

10.12 Audit Program

	We will annually review the content and implementation of the radiation protection program to ensure compliance with Agency and applicable DOT regulations; the terms and conditions of the license; occupational doses; and doses to members of the general public are ALARA. (Appendix L to NUREG 1556, Vol. 9 or equivalent)

10.13 Operating And Emergency Procedures

	We have developed and will implement, and maintain specific operating and emergency procedures. (Appendix N to NUREG 1556, Vol. 9. or equivalent)

10.14 Material Receipt And Accountability

	We will secure licensed material.
	We will maintain records of receipt, transfer, and disposal of licensed material.
	We will conduct physical inventories at required frequencies to account for licensed material.

10.15 Ordering And Receiving

	We will ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, we will ensure that packages are secured and radiation exposure from packages is minimized. (Appendix O to NUREG 1556, Vol. 9. or equivalent)

10.16 Sealed Source Inventory

	We will conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources (individual GSR sources are exempt) in our possession**.**

	We will maintain records of GSR source receipt, transfer, and disposal to indicate the current inventory of sources at our facility.

10.17 Records Of Dosages And Use Of Brachytherapy Source

	We will make and maintain the records of each dosage and administration prior to medical use.

	We will make and maintain the appropriate records for molybdenum concentrations.

	We will make and maintain the appropriate records for the manual use of brachytherapy sources.

10.18 Recordkeeping

	We will maintain records as provided in Subpart L to Part D, and Subpart L to Part G. (Appendix X to NUREG 1556, Vol. 9.)

10.19 Reporting

	We will report to the Agency incidents that might compromise the health and safety of patients, health care providers, or the public as required in Subpart M to Part D. and Subpart M to Part G. (Appendix Y to NUREG 1556, Vol. 9.)

	We will report to the Agency by telephone immediately and followed by a written report within 30 days any event tin which the security of radioactive material is compromised.

10.20 Leak Tests

	We will perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with G.27. (Appendix Q to NUREG 1556, Vol. 9 or equivalent)

10.21 Safety Procedures For Treatments When Patients Are Hospitalized

	We have developed and will implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the general public within regulatory limits. (G.30, G.302, G.404, G.604)

10.22 Transportation

	We have developed and will implement and maintain a safety program for the transport of radioactive materials to ensure compliance with State and Federal regulations. (Appendix Z to NUREG 1556, Vol. 9)

11. WASTE MANAGEMENT: Waste Disposal

	We have developed and will implement and maintain written disposal procedures for licensed material in accordance with Part D.5, that also meet the requirements of the applicable section of Subpart K to Part D. and G.32. (Appendix W to NUREG 1556, Vol. 9. or equivalent)

12. CERTIFICATION: The applicant and any official executing this certificate on behalf of the applicant named in item 2, certify that this application is prepared in conformity with the State of Maine Rules Relating to Radiation Protection and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

DATE:_____ SIGNATURE OF APPLICANT:_____

TITLE:_____ TYPED/PRINTED NAME:_____